

CERTIFICATES OF CONFIDENTIALITY**Description**

Certificates of Confidentiality (CoCs) are intended to protect the privacy of research subjects by prohibiting disclosure of identifiable, sensitive information to anyone not connected to the research except when the subject consents, or in a few other specific situations. CoCs are issued by the National Institutes of Health (NIH) and other Health and Human Services agencies. All ongoing or new research funded by NIH (as of December 13, 2016), that is collecting or using identifiable, sensitive information is automatically issued a Certificate of Confidentiality. In some cases, a researcher can apply for a CoC from NIH (see below for more information).

A CoC provides protection for the Investigator and the participants against compelled disclosure of identifying information about participants of biomedical, behavioral, clinical, and other research. This means that Investigators may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify their participants.

CoCs do not take the place of good data security or clear policies and procedures for data protection, which are essential to the protection of research participants' privacy. Researchers should take appropriate steps to safeguard research data and findings. Unauthorized individuals must not access the research data or learn the identity of research participants.

CoCs do not protect information voluntarily disclosed or information that must be disclosed under mandatory reporting laws. Examples include voluntary disclosures by the participant themselves or disclosures to which the participant has consented. Mandatory disclosures include disclosures on matters such as child abuse, reportable communicable diseases, or possible threat to self or others.

NIH-Funded Research

If your NIH-funded research meets any of the following criteria, then the research data or information is automatically protected by a CoC from NIH:

- Meets the definition of human subjects' research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk¹ of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information² that identify a person

NIH does not issue a physical certificate for NIH-funded research projects. The [NIH CoC Policy](#), Notice of Award, the [NIH Grants Policy Statement](#) for grant awards, and the [NIH DGS Contract Handbook- Special Contracts Requirements](#) for R&D Contracts, provides documentation of the CoC protection.

Non-NIH Funded Research

Health-related research that is not federally funded or funded by a non-Health and Human Services federal agency in which identifiable, sensitive information is collected or used, may request a Certificate of Confidentiality (CoC) for specific projects. Issuance of a CoC for non-federally-funded research continues to be at the discretion of NIH.

Certificates of Confidentiality are only issued for research projects that are:

- Collecting or using identifiable, sensitive information (see below for more detail)
- On a topic that is within the HHS health related research mission

¹ At least a very small risk that some combination of the biospecimen, a request for the biospecimens, and other available data sources could be used to deduce the identity of an individual.

² Information about an individual for which there is at least a very small risk, as determined by current scientific practice or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of the individual.

Please contact the OPRS Office at (217) 333-2670 or irb@illinois.edu for additional guidance.

- Storing the research information collected or used in the US

Research in which identifiable, sensitive information is collected or used, including research that:

- Meets the definition of human subjects' research, including exempt research in which subjects can be identified
- Is collecting or using human biospecimens that are identifiable or that have a risk of being identifiable
- Involves the generation of individual level human genomic data
- Involves any other information that might identify a person

Several non-NIH HHS agencies, including CDC, FDA, HRSA, and SAMHSA, issue Certificates of Confidentiality (CoCs). If your research is funded by one of these agencies or is operating under the authority of the FDA, please contact the Certificate Coordinators at the funding agency to determine how to obtain a CoC.

Exceptions

The Agency for Healthcare Research & Quality (AHRQ) has its own privacy regulations which may apply; NIH will not issue a CoC for projects covered by AHRQ's regulations. Contact [AHRQ](#) for further information about their privacy regulations.

The Department of Justice (DoJ) has its own confidentiality and privacy regulations for DoJ-funded research. NIH will not issue a CoC for DoJ-funded projects. Contact the [DoJ](#) for additional information about their confidentiality and privacy regulations.

Application for a CoC

<https://public.era.nih.gov/commonsplus/public/coc/request/init.era>

Please note for non-NIH funded projects the Institutional Official is required to approve the request on behalf of the University of Illinois Urbana-Champaign. The UIUC Institutional Official is the Vice Chancellor for Research Compliance and Innovation.

Points to Address

New Study Application:	1. Data Monitoring Page, Confidentiality Precautions: Please select "A Certificate of Confidentiality (from the NIH) will be used".
Consent Document:	1. Confidentiality: If a Certificate of Confidentiality is valid for your study, briefly provide participants with a clear explanation of the protection that the Certificate of Confidentiality affords, including the limitations and exceptions . Also, ensure that an explanation of how identifiable information will be used or disclosed is provided. (NIH provides sample consent language here: https://grants.nih.gov/policy/humansubjects/coc/suggested-consent.htm)

References & Links

Application for a Certificate of Confidentiality <https://public.era.nih.gov/commonsplus/public/coc/request/init.era>

Certificate of Confidentiality Information <https://grants.nih.gov/policy/humansubjects/coc.htm>

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Office for the Protection
of Research Subjects

Research Guidance Document

*Investigator and Institutional
CoC Responsibilities*

<https://grants.nih.gov/policy/humansubjects/coc/information-institutional-responsibilities.htm>

*Who Can Get a Certificate of
Confidentiality*

<https://grants.nih.gov/policy/humansubjects/coc/who-can.htm>

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